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10/601,476

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Edwin G. Duffin

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

09/13/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/601,476

Applicant(s)

DUFFIN ET AL.

Examiner

Michael Kahelin

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) 21-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-9 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 26 are hybrid claims, reciting a method step in an apparatus claim. This renders the claim vague because it is unclear whether an apparatus or method is being claimed. Further, if the "wherein" clause is a functional limitation to an apparatus claim, "being selected" and "in response to one of lowest attainable threshold and absence of phrenic nerve stimulation" are vague because nothing has been set for the "select" or measure lowest attainable threshold or absence of phrenic nerve stimulation. As the amended "whereby" clause imparts no structural limitation to the claimed apparatus, the Examiner is considering the clause to be an intended use recitation.

6/30/17

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sluetz et al. (US Re. 31,990), in view of Goldreyer (US 4,365,639, hereinafter "Goldreyer").

Sluetz discloses a system comprising an array of electrodes (68 and 69), an assembly of insulated conductors (65), a lead connector with a linear array of contacts to select an electrode (Fig. 1), a pulse generator with a connector bore (18) wherein at each position of the lead connector, a lead connector contact makes connection with the connector bore contact (16) to make a corresponding one of the electrodes as a connected active electrode because it is in communication with the device electronics, and a means for reversibly locking the connector along multiple positions in the bore (col. 6, line 21, and 25). Sluetz does not disclose that the electrodes are distributed circumferentially on the lead body. Goldreyer teaches of providing a system having pacing lead with multiple selectable, circumferentially spaced electrodes (21-24) to sense in a very specific area to determine local effects. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Sluetz's invention

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with a pacing lead with multiple selectable, circumferentially spaced electrodes to provide the predictable result of sensing in a very specific area to determine local effects. Further, Sluetz' invention is capable of meeting the intended use "wherein" clause because any of the electrodes can be selected, including the one having the lowest threshold.

6. Claims 1-3, 5, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sluetz et al. (US Re. 31,990), in view of Doan et al. (US 7,031,774, hereinafter "Doan") and Goldreyer (US 4,365,639, hereinafter "Goldreyer"). Sluetz discloses the essential features of the claimed invention including the following:

7. In regards to claims 1 and 3, Sluetz discloses a system comprising an array of electrodes (68 and 69), an assembly of insulated conductors (65), a lead connector with a linear array of contacts to select an electrode (Fig. 1), a pulse generator with a connector bore (18) wherein at each position of the lead connector, a lead connector contact makes connection with the connector bore contact (16) to make a corresponding one of the electrodes as a connected active electrode because it is in communication with the device electronics, and a means for reversibly locking the connector along multiple positions in the bore (col. 6, line 21, and 25). Further, Sluetz' invention is capable of meeting the intended use "wherein" clause because any of the electrodes can be selected, including the one having the lowest threshold.

8. Sluetz does not disclose that, at each position of the lead connector, a first contact and third contact are electrically connected to the pulse generator and a second contact is electrically disconnected from the pulse generator. Doan teaches of providing

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a sliding electrode selection means wherein at each position of the lead connector, a first contact and third contact are electrically connected to the pulse generator and a second contact is electrically disconnected from the pulse generator (Figs. 4 and 5) to allow various combinations of electrodes to be in electrical communication with the pulse generator, thusly allowing the location of stimulation to be adjusted after final lead implantation. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Sluetz' invention by providing a sliding electrode selection means wherein at each position of the lead connector, a first contact and third contact are electrically connected to the pulse generator and a second contact is electrically disconnected from the pulse generator to provide the predictable result of allowing both the polarity and location of stimulation to be adjusted after final lead implantation.

9. Further, Sluetz does not disclose that the electrodes are distributed circumferentially on the lead body. Goldreyer teaches of providing a system having pacing lead with multiple selectable, circumferentially spaced electrodes (21-24) to sense in a very specific area to determine local effects. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Sluetz's invention with a pacing lead with multiple selectable, circumferentially spaced electrodes to sense in a very specific area to provide the predictable result of determining local effects.

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10. In regards to claim 2, the connector comprises a second contact to make a second electrode as a connected active electrode because it is connected to the internal electronics (17).

11. In regards to claim 5, the means for locking the connector includes a deflectable member projecting into the bore (25).

12. In regards to claim 9, the means for locking includes an actuated member (27 and col. 6, line 3).

13. Claims 4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sluetz in view of Doan and Goldreyer, as applied to claim 1 above, and further in view of Bischoff et al. (US 5,843,141, hereinafter "Bischoff"). Sluetz's modified invention discloses the essential features of the claimed invention except for an insertion tool and a set of spacers with surface depressions in which deflectable members rest. Bischoff teaches of providing a multiple connector lead system with an insertion tool to easily pull the lead into cooperation with the energy applicator and a set of spacers with surface depressions in which deflectable members rest to electrically isolate the electrodes and provide a fixation means for the lead. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Sluetz's modified invention with an insertion tool to easily pull the lead into engagement with the energy applicator and a set of spacers with surface depressions in which deflectable members rest to provide the predictable results of electrically isolating the electrodes

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and providing a fixation means for the lead. Please note that the surface depressions can be seen in Figure 6.

14. Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sluetz in view of Doan and Goldreyer, as applied to claim 1 above, and further in view of Peers-Trevarton (US 4,469,104, hereinafter "Peers-Trevarton"). Sluetz's modified invention discloses the essential features of the claimed invention except for deflectable members that rest in surface depressions on the contacts and deflectable members that rest in depressions apart from the array of contacts. Peers-Trevarton teaches of providing a multiple electrode connection device with deflectable members that rest in surface depressions on contacts (140) to ensure a close electrical communication between the two contacts and deflectable members that rest in depressions apart from the array of contacts (101) to create a barrier between fluids and the contacts and provide a tight fit for the lead in the bore. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide Sluetz's modified invention with deflectable members that rest in surface depressions on contacts to provide the predictable results of ensuring a close electrical communication between the two contacts and deflectable members that rest in depressions apart from the array of contacts to create a barrier between fluids and the contacts and provide a tight fit for the lead in the bore. Please note that the examiner is interpreting the surface depression in which the deflectable member rests is the unlabelled feature in proximity to element 172 in Figure 1.

Response to Arguments

15. Applicant's arguments filed 7/16/2007 have been fully considered but they are not persuasive. In response to applicant's argument that Goldreyer's electrodes are not selectable, please see the end of column 4 to the top of column 6 for Goldreyer's disclosure of selecting various electrode combinations to determine local effects.

16. In response to applicant's argument that various features of Sluetz, Goldreyer and Doan are incompatible, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). As such, the Examiner maintains the rejections of 2/14/2007.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

MLR
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~ c'
GEORGE R. EVANISKO
PRIMARY EXAMINER

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